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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,603	09/29/2003	Eric C. Luo	43305.12.0.43.1 fka 3200-	6336

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,603	LUO ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *15,16 and 22-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/29/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS filed 09/29/2003, and election 01/04/2007.

Claims 1-42 are pending.

Response to Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-14, 17-21, species (a) of inorganic hydroxide, and species (a) of local anesthetic in the reply filed on 01/04/2007 is acknowledged. The traversal is on the ground(s) that the office action fails to provide basis for reasons why the inventions are distinct. Applicants further argue that different structure of different species does not support an election requirement. This is not found persuasive because the office action stated clearly the distinction between invention I and invention II because invention I is a composition that does not have any specific structure or formulation and can be in the form of cream, lotion or ointment, while invention II requires specific structure of a device comprising reservoir, backing layer and means for maintaining the system in contact with the body surface, and further invention II requires specific formulation comprising adhesive polymer or hydrogel that are not required by invention II. Therefore, inventions I and II will have different modes of operation based on their different designs. Regarding the different

species of hydroxide releasing agent and anesthetic, it is argued that searching different species having distinct chemical structure constitutes burden on the patent examiner, and the prior art that anticipate one species may not anticipate the other.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15, 16, 22-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/04/2007.

Claims 1-14, 17-22 are included in the prosecution.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,582,724. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of the issued patent are directed to the common subject matter as follows: topical or transdermal formulation comprising hydroxide releasing agent, carrier, and local anesthetic. The local anesthetics are recited in claim 37 of the issued patent. Therefore, the claims of the issued patent anticipate the present claims.

5. Claims 1-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,673,363. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of the issued patent are directed to the common subject matter as follows: topical or transdermal formulation comprising hydroxide releasing agent, carrier, and local anesthetic. Therefore, the claims of the issued patent anticipate the present claims.

6. Claims 1-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,835,392. Although the conflicting claims are not identical, they are not patentably distinct from

each other because the present claims and the claims of the issued patent are directed to the common subject matter as follows: topical or transdermal formulation comprising hydroxide releasing agent, carrier, and local anesthetic. The local anesthetics are recited in claim 43 of the issued patent. Therefore, the claims of the issued patent anticipate the present claims.

7. Claims 1-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,586,000 in view of US 5,993,836 ('836). The present claims and the claims of the issued patent are directed to the common subject matter as follows: topical or transdermal formulation comprising hydroxide releasing agent and active agent.

The difference between the present claims and the claims of the issued patent is that the issued claims do not recite local anesthetic as the drug to be delivered by the claimed device and method.

US '836 teaches topical and transdermal delivery of local anesthetics that is have rapid onset and additionally convenient and not messy (col.3, lines 25-30, 37-39).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver topical or transdermal formulation comprising hydroxide releasing agent and active agent as claimed by US '836, and replace the active agent by local anesthetic as disclosed by US '836, motivated by the teaching of US '836 that local anesthetics are desirable to be delivered transdermally or topically to provide rapid onset of local anesthesia, with reasonable expectation of having topical or

transdermal formulation comprising hydroxide releasing agent and local anesthetic that has rapid onset of action to relieve pain rapidly and effectively from the patient in need of such treatment.

8. Claims 1-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 51-52 of copending Application No. 10/863,432. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: the present claims and the claims of the copending application are directed to the common subject matter as follows: topical or transdermal formulation comprising hydroxide releasing agent and local anesthetic.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Regarding claims 19 and 20, the expression "derivatives" does not set out the metes and bounds of the claim. Recourse to the specification does not define the expression. With regard to claim 21, the expression "irritation mitigating" does not set out the metes and bounds of the claim. Recourse to the specification does not define the expression.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4, 9, 11, 13, 14, 17, 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,938,970 ('970).

The present claims are directed to topical composition comprising local anesthetic, carrier, sodium hydroxide, wherein the composition has pH of 8.0-13.0.

US '970 teaches aqueous solution for topical composition comprising local anesthetic including lidocaine, and sodium hydroxide to bring the pH of the composition to 6.85-8.0 (abstract; col.3, lines 20-30, 42-43; col.6, lines 7-10). The composition further comprises cations which read on irritating mitigating agent, in absence of disclosure of any irritation mitigating agents (col.3, lines 39-40). The teaching of the reference implies using both acidic and non-acidic species of the anesthetic.

The limitation of the rejected claims are met by US '970.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 5-8, 10, 12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '970.

The teachings of US '970 are discussed above.

However, US '970 does not teach pH over 8.0 as claimed by claims 5 and 18, the formulation as claimed by claim 6, the amount of enhancement of the delivery as claimed by claims 7 and 8, or the amount of hydroxide releasing agent as claimed by claims 10 and 12.

Regarding such values of pH and amounts of hydroxide releasing agent, one having ordinary skill in the art would have determined such amounts according to specific intended use. Regarding enhancement of the delivery of the formulation, it is expected to be the same from formulation having the same ingredients. Further, topical formulations such as gel, lotions and creams are all known for topical use.

Therefore, it would have been obvious to one having ordinary in the art at the time of the invention to provide topical aqueous formulation comprising local anesthetic and hydroxide releasing agent having pH value up to 8.0, and further adjust the amount of the hydroxide releasing agent according to the specific site of application to obtain the desired pH in order to achieve safe topical formulation.

16. Claims 1-14, 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,830,497 ('497).

US '497 teaches medicated plaster having an exposed surface with pH of 7.0 or higher comprising active agent including lidocaine hydrochloride (abstract; col.7, lines 7-9; col.9, lines 15-17). PH is adjusted using sodium hydroxide (col.8, lines 65-67). US '497 teaches using basic substance in an amount of 0.1 to 10 moles per mole of medicine (col.9, lines 5-7). This teaching implies that the amount of the basic substance is not only to neutralize the medicine, but can be as much as 10 times more than the medicine casing alkaline pH when neutralizing the formulation.

US '497 does not teach specific pH over 8.0 as claimed, the formulation as claimed by claim 6, the amount of enhancement of the delivery as claimed by claims 7 and 8, or the amount of hydroxide releasing agent as claimed by claims 10 and 12.

Regarding such values of pH and amounts of hydroxide releasing agent, one having ordinary skill in the art would have determined such amounts according to specific intended use. Regarding enhancement of the delivery of the formulation, it is expected to be the same from formulation having the same ingredients. Further, topical formulations such as gel, lotions and creams are all known for topical use.

Therefore, it would have been obvious to one having ordinary in the art at the time of the invention to provide topical formulation comprising local anesthetic and hydroxide releasing agent having pH value higher than 7.0, and further adjust the amount of the hydroxide releasing agent according to the specific site of application to obtain the desired pH in order to achieve safe topical formulation.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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